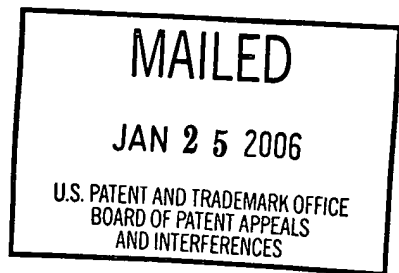


The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES



Ex parte LARS MORCH GROTH

Appeal No. 2005-2537  
Application No. 09/921,429

ON BRIEF

Before McQUADE, NASE and BAHR, Administrative Patent Judges.  
McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Lars Morch Groth appeals from the final rejection of claims 19-22, all of the claims pending in the application.<sup>1</sup>

THE INVENTION

The invention relates to a magazine for storing and dispensing medical injection needle assemblies wherein the magazine is designed to be used as a tool for connecting the needle assemblies to injection devices. Representative claim 19 reads as follows:

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<sup>1</sup> Claim 22 has been amended subsequent to final rejection.

19. A tool for attaching a pen needle assembly, which comprises a hub and needle cannula mounted to the hub, to an injection device that has a needle mounting surface disposed thereon, the tool comprising:

a. a cylindrical storage member having elongated cavities complementary in size and shape to the pen needle assembly, the cavities arranged radially in the cylindrical member so as to allow the tool to rotate about an axis of rotation that is concentric with the cavity's longitudinal axis;

b. a rotatable cover mounted on the storage member having a cylindrical wall and having an opening that allows access to one cavity at a time;

c. a remov[able] sterility barrier sealing the cavities;

wherein: the height of the cylindrical member and cover are sized so as to allow a user to grasp the tool in one hand and to rotate the tool in one hand 360 degrees about the axis of rotation while simultaneously allowing the user to rotate the injection device 360 degrees in an other hand, wherein when the tool is grasped in the hand of a user, the majority of rotational force applied to the tool occurs at a distance displaced away from the axis of rotation of the tool, thereby maximizing the rotational force on the pen needle assembly[.]

#### THE PRIOR ART

The references relied on by the examiner to support the final rejection are:

Current	4,203,518	May 20, 1980
Nguyen et al. (Nguyen)	5,873,462	Feb. 23, 1999

### THE REJECTION

Claims 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nguyen in view of Current.

Attention is directed to the main and reply briefs (filed January 26, 2005 and April 13, 2005) and the final rejection and answer (mailed July 29, 2004 and February 24, 2005) for the respective positions of the appellant and examiner regarding the merits of this rejection.

### DISCUSSION

Nguyen, the examiner's primary reference, discloses "an apparatus that holds and dispenses sterile pen needles for medication delivery pens and that safely stores the needles after use" (column 1, lines 6-8). The apparatus takes the form of a pen needle dispenser 10 comprising a container 30 and a cover 20. The container includes a circular array of vertically oriented, open top cavities 31 housing respective pen needle assemblies 100, peelable sterility barriers 150 sealing the open tops of the cavities, and a series of splines 44 within the cavities for engaging complementary channels 108 on the pen needle assemblies to prevent the assemblies from rotating within the cavities. This latter feature facilitates the threaded connection of the pen needle assemblies to pen injection devices (see column 5,

lines 31-37). The cover 20, which is a disc-like member rotatably mounted on the upper surface of the container, contains a slot 21 for accessing the cavities one at a time. The cover and container also comprise respective ratchet teeth 25 and 33 and lock pins or keys 26 and 36 which cooperate to limit rotation of the cover to not more than 360 degrees in but a single direction to prevent used pen needle assemblies which have been placed back into their cavities from being reused.

As conceded by the examiner (see pages 2-4 in the final rejection), Nguyen does not respond to the limitations in independent claims 19, 21 and 22 relating to the orientation of the cavities and the shape of the cover. As indicated above, claim 19 requires the cavities to be arranged radially in the cylindrical member and the rotatable cover to have a cylindrical wall. Claim 21 recites a method of mounting a pen needle assembly comprising, inter alia, the step of obtaining a tool that includes a cylindrical storage member having cavities arranged radially and a rotatable cover having a cylindrical wall, and claim 22 recites a needle storage and mounting apparatus comprising, inter alia, a cylindrical body having radial cavities and a cylindrical cover. As set forth in the underlying specification, and to some extent in claims 19, 21 and 22, these features facilitate the connection of a

pen needle assembly to an injection device by allowing the tool or apparatus to be grasped in one hand and rotated 360 degrees about an axis of rotation concentric with the longitudinal axis of a radial cavity while the injection device is grasped in the other hand and rotated 360 degrees.

To overcome the admitted deficiencies of Nguyen relative to the subject matter recited in independent claims 19, 21 and 22, the examiner turns to Current.

Current discloses "a package for retaining and dispensing sewing machine needles" (column 1, lines 6-7). The package comprises a circular storage disc 12 and a rotatable base or cover 24. The storage disc 12 includes a plurality of radial and circumferential walls 16 and 20 which define a plurality of needle storage compartments 18 open at their tops and radial outer ends. The rotatable base 24 consists of a circular surface 26 covering the open tops of the needle storage compartments, a downwardly extending cylindrical base wall 28 covering the open outer ends of the needle storage compartments, and a dispensing slot 34 in the cylindrical base wall for accessing the needle storage compartments one at a time to allow needles to be inserted into and removed from the storage compartments.

In combining Nguyen and Current to reject independent claims 19, 21 and 22, the examiner submits that

[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tool of Nguyen et al by rotating the vertical compartments to the horizontal position and providing the magazine with radial extending cavities and a cover as taught by Current in order to reduce the overall height of the container. Such a modification is deemed a mere rearrangement of parts, and it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70 [final rejection, page 3].

Responding to the appellant's argument that Nguyen and Current would not have suggested this modification, the examiner also contends that

[i]n this case, the motivation can be found in the knowledge that was generally available to one of ordinary skill in the art at the time the invention was made, where it was a well established principal of design for portable objects to limit overall size. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955) [answer, page 5].

The examiner's position here is unsound. To begin with, the combined teachings of Nguyen and Current contain no indication that the height or size of the Nguyen device is a problem or that a reduction thereof would be advantageous. Indeed, it is not even clear that the proposed modification of the Nguyen device would result in any significant reduction in its height or overall size.

The references also fail to show any appreciation of the pen needle assembly connection benefits afforded by the radially disposed cavities of the appellant's invention. In this light, it is evident that the only suggestion for combining Nguyen and Current in the manner advanced by the examiner stems from hindsight knowledge impermissibly derived from the appellant's disclosure. The evidentiary deficiencies in the applied references find no cure in the examiner's reliance on ambiguous averments of knowledge generally available in the art and/or general rules of obviousness relating to changes in size and rearrangement of parts. Bald assertions of common knowledge are not a substitute for the evidence necessary to support a conclusion of obviousness. See In re Lee, 277 F.3d 1338, 1345, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002). Furthermore, the use of per se rules of obviousness is legally erroneous because it sidesteps the fact-specific analysis mandated by § 103(a). See In re Ochiai, 71 F.3d 1565, 1571-1572, 37 USPQ2d 1127, 1132-33 (Fed. Cir. 1995).

For these reasons, Nguyen and Current do not justify the examiner's conclusion that the differences between the subject matter recited in independent claims 19, 21 and 22 and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having


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ordinary skill in the art. Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claims 19, 21 and 22, and dependent claim 20, as being unpatentable over Nguyen in view of Current.

## SUMMARY

The decision of the examiner to reject claims 19-22 is reversed.

REVERSED

  
JOHN P. McQUADE  
Administrative Patent Judge

  
JEFFREY V. NASE  
Administrative Patent Judge

BOARD OF PATENT  
APPEALS  
AND  
INTERFERENCES

  
JENNIFER D. BAHR  
Administrative Patent Judge



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